

REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated July 14, 2004 are respectfully requested.

I. Amendments

Claims 1, 10, and 20 are amended to recite selectively advancing the electrodes for consistent terminology. Basis for this amendment can be found on page 12, line 23 through page 13, line 5, and in Fig. 22.

Claim 20 is further amended to recite an advancement device coupled to the energy delivery device, the advancement device configured to selectively advance individual electrodes of the plurality of electrodes from the housing interior to a selected deployment depth. Basis for this amendment can be found on page 14, lines 1-2 and on page 12, line 23 through page 13, line 5, and in Fig. 22.

By these amendments, no new subject matter has been added.

II. Rejection under 35 U.S.C. §112, first paragraph

Claims 10-19 were rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

These rejections are respectfully traversed.

A. Written Description

Specifically, the Examiner asserts that the specification fails to provide an adequate written description of an expandable member positioned at the distal end of the housing.

1. Legal Standard for Written Description

According to MPEP 2163.02, an objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

2. Meeting the Legal Standard

Applicants respectfully direct the Examiner to page 21, lines 12-18, where an inflatable porous section is described. As seen in Figures 12A and 12B, this inflatable porous section is positioned at the distal end of the housing. Applicants further direct the Examiner to page 63, lines 17-19 and page 65, lines 15-17, where another embodiment of an expandable member is described as an expansion device positioned at the distal end of the housing.

Thus, Applicants clearly describe and show an expandable member positioned at the distal end of the housing as presently claimed.

Accordingly, one skilled in the art would reasonably conclude, in light of the specification, that Applicants were in possession of the claimed invention at the time the invention was filed.

III. Rejection under 35 C.F.R. §102

Claims 1-7 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by *Cosman et al.* (U.S. Patent No. 6,530,922).

These rejections are respectfully traversed.

A. The Present Invention

The present invention, as embodied by claim 1, describes a method of controlling an ablation volume depth during surface treatment comprises (a) providing an apparatus, where the apparatus comprises (i) a housing having a proximal end and a distal end including a tissue contacting surface having at least one aperture, and the housing defines an interior, (ii) an energy delivery device including a plurality of electrodes, each with a tissue penetrating distal end, the plurality of electrodes configured to be advanced from the housing interior through the at least one aperture and into a target tissue site to define an ablation volume at least partly bounded by the tissue surface, (iii) an advancement device coupled to the energy delivery device, where the advancement device is configured to selectively advance individual electrodes of the plurality of electrodes from the housing interior to a selected deployment depth. The method further comprises (b) positioning the tissue contact surface on a target tissue surface, (c) selectively advancing the plurality of electrodes using the advancement device to the selected deployment depth beneath a tissue surface while avoiding a critical structure, (d) delivering ablative energy from the energy delivery device (e) creating an ablation volume at a controlled depth below the tissue surface responsive to the electrode advancement device, and (f) minimizing injury to the critical structure responsive to the electrode deployment depth.

B. The Prior Art

COSMAN ET AL. describe various configurations of a cluster array of electrodes for producing large ablation volumes in body tissue (Col. 3, lines 50-54). In one embodiment, the system includes a cluster electrode array inserted into the tissue using a guide block with multiple hold templates or by stereotactic guidance (Col. 7, lines 15-19). In another embodiment, the system includes an integral hub where the proximal ends of the electrode shafts are fixedly positioned in the hub (Col. 9, lines 4-5; Col. 10, line 61 through Col. 11, line 3). Finally, the instrument may include two electrodes attached to a plunger unit, which slides in a carrier or sheath (Col. 12, lines 28-34).

C. Analysis

According to the M.P.E.P. § 2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference".

Cosman *et al.* fail to teach providing an apparatus comprising an advancement device, where the advancement device is configured to selectively advance individual electrodes of the plurality of electrodes from the housing interior to a selected deployment depth.

The only teachings in Cosman *et al.* that could be considered an advancement device are (i) the hub structure (Col. 9, lines 4-5), and (ii) the plunger unit (Col. 12, lines 28-30 and 34-38). Regarding the hub structure, as seen in Figure 10, Cosman *et al.* state that the proximal ends of the electrode shafts are "fixed mechanically" in the hub (Col. 15, lines 57-59). Thus, the hub structure cannot selectively advance individual electrodes as presently claimed. Concerning the plunger unit, as seen in Fig. 7, the electrodes are attached to the plunger unit, which in turn slides in a carrier or sheath. Describing the deployment of the electrodes using the plunger, Cosman *et al.* state "[i]n this way, the carrier may be manually held to the organ surface, and the electrodes 130 and 131 pushed in unison into the tissue to show that their tips 132 and 133 reach the targeted volume 135" (Col. 12, lines 34-38, emphasis added). Thus, the plunger unit does not selectively advance individual electrodes as presently claimed.

Thus, Cosman *et al.* fail to teach each and every element as set forth in the claim is found, either expressly or inherently as required to support a rejection under 37 CFR 102.

Examiner's Arguments

The Examiner cites Col. 15, lines 42-44 of Cosman *et al.*, "where various mechanisms that are capable of selectively advancing individual electrodes are disclosed" (Office action mailed July 14, 2004, page 3) as a teaching of an apparatus comprising an advancement device, where the advancement device is

configured to selectively advance individual electrodes of the plurality of electrodes from the housing interior.

Applicants' Rebuttal

Applicants respectfully disagree that the above referenced citation teaches an apparatus comprising an advancement device, where the advancement device is configured to selectively advance individual electrodes of the plurality of electrodes from the housing interior. Cosman *et al.* state "[s]equential or parallel insertion of electrode arrays such as 214, 216, and 220 may be made using free hand, stereotactic, guide block, digitizer navigator, or ultrasonic, MRI, or CT control." None of these techniques provide a teaching of providing an apparatus comprising an advancement member configured to selectively advance individual electrodes of the plurality of electrodes from the housing interior.

While, the free hand technique, the use of a stereotactic guide, a guide block, a digitizer navigator, or an ultrasonic, MRI, or CT imager *could* include sequential insertion of electrodes (Col. 15, lines 42-45), these techniques and guides each fail to teach providing a treatment apparatus including "an advancement device coupled to the energy delivery device, the advancement device configured to selectively advance individual electrodes of the plurality of electrodes from the housing interior to a selected deployment depth" as presently claimed.

Free hand insertion of the electrode array certainly does not include selectively advancing the electrodes with an advancement device by the very nature of the technique. The electrodes are advanced by hand and not by an advancement device.

Stereotactic guidance and a guide block, as seen in Figs. 1 and 10, merely provide an external guide for placement of the electrodes. Neither of these systems provide an apparatus with an advancement device, much less an advancement device configured to selectively advance individual electrodes to a selected deployment depth.

Similarly, a digitizer navigator, ultrasonic, MRI, and CT are imaging systems to assist the operator in determining placement of the electrodes and in no way teach providing an apparatus with an advancement device, much less an advancement device configured to selectively advance individual electrodes to a selected deployment depth.

Accordingly, Applicants submit that standard of strict identity to maintain a rejection under 35 U.S.C. § 102 has not been met. Withdrawal of the rejections under 35 U.S.C. § 102(e) is respectfully requested.

IV. Rejections under 35 C.F.R. §103

Claims 8, 9, and 20 were rejected under 35 U.S.C. §103 as allegedly obvious over Cosman *et al.* further in view of Behl *et al.* This rejection is respectfully traversed.

A. The Present Invention

The present invention, according to claims 8 and 9, is described above. The method according to claim 20 also includes a step of providing a tissue surface treatment apparatus comprising an advancement device coupled to the energy delivery device, the advancement device configured to selectively advance individual electrodes of the plurality of electrodes from the housing interior to a selected deployment depth.

B. The Prior Art

COSMAN ET AL. is described above.

BEHL ET AL. describe a system for treatment of target region beneath a tissue surface comprising a probe for deploying an electrode array within the tissue and a cover for engaging the tissue surface above the treatment site. The cover may be a rigid plate and may be clipped or otherwise removably attached to the probe. The cover may comprise electrode(s) or be electrically neutral.

Analysis

According to the MPEP § 2143, "to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references (or references when combined) must teach or suggest all the claim limitations."

As noted above, Cosman *et al.* fail to teach providing tissue surface treatment apparatus including an advancement device, where the advancement device is configured to selectively advance individual electrodes of the plurality of electrodes from the housing interior to a selected deployment depth.

The teaching in Behl *et al.* does not make up for this deficiency in Cosman *et al.* as Behl *et al.* does not even teach advancing a plurality of surface electrodes from at least one aperture in a housing, much less selectively advancing individual electrodes. The system of Behl *et al.* includes a cover deployed over the tissue surface to secure a probe that is used to introduce a plurality of electrodes to a tissue site. The cover can be a surface electrode to provide monopolar ablation with the plurality of electrodes at the tissue site. However, as seen in Fig. 4, the surface electrode is not advanced through an aperture in a housing.

Thus, nowhere does either reference, taken alone or in combination, show or suggest selectively advancing individual electrodes of a plurality of electrodes to a selected deployment depth.

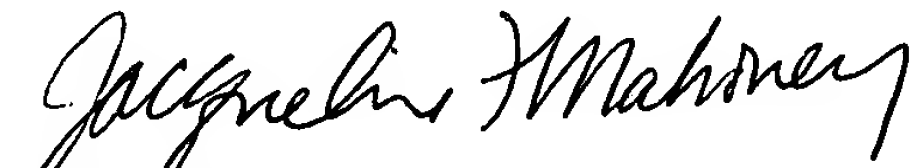
Because none of the references alone or in combination teach all the claim limitations of the present invention, the standard for obviousness has not been met. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

V. CONCLUSION

In view of the foregoing, Applicants submit that the claims pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

The Examiner is invited to contact Applicants' representative at (650) 838-4410 if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,


Jacqueline F. Mahoney
Registration No. 48,390

Date: Sept. 14, 2004

Correspondence Address:

Customer No. 22918
(650) 838-4300